IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-op-45090 and *The County of Cuyahoga v. Purdue Pharma L.P., et al.* Case No. 1:18-op-45004	)	MDL No. 2804 Hon. Judge Dan A. Polster

<u>MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE LACEY KELLER'S OPINIONS AND PROPOSED TESTIMONY</u>

Plaintiffs' expert Lacey Keller is a data analyst with training in economics who concedes that she has no substantive experience or expertise in the Controlled Substances Act, the DEA, or the federal regulations governing suspicious order monitoring. Ex. 1, Keller Tr. 48:3-50:13. Nevertheless, Keller applies 16 "compliance metrics," *i.e.*, various suspicious order monitoring algorithms, to certain IQVIA[1] and chargeback data[2] to identify what she deems "suspicious orders," even though she admits that she used the term differently than it is used in the CSA and related DEA regulations. Specifically, Ms. Keller purports to calculate: (1) how many prescriptions supposedly could have been identified by Manufacturer Defendants through IQVIA data (the "Prescriber" opinion); and (2) how many orders of opioid medications supposedly could have been identified through chargeback data (the "Chargeback" opinion). Keller concludes that "there were millions of prescriptions and purchases of billions of dosage units and MMEs in Cuyahoga and Summit counties that defendant manufacturers of opioids . . . could have identified as being of unusual size or frequency and deviating from the normal pattern yet were unreported." Ex. 2, Keller Rep. ¶ 27; *see also* Ex. 1, Keller Tr. 88:13-22, 90:10-17, 96:9-17.

In addition, in her separate "Small Labeler Impact" opinion, Keller applies a variation of her Prescriber analysis to Janssen—which has a minuscule market share she calculated as between 0.1 to 0.9 percent in the Track One jurisdictions. She purports to calculate how many opioid prescriptions could have been stopped if Janssen had reported the activity of prescribers

[1] Keller describes the IQVIA Xponent® data she used as "data from a representative sample of pharmacies, mail order services, and long term care facilities. The dataset, owned and maintained by IQVIA—a healthcare information company—is used by industry 'to measure market and product demand.' On the company's website, IQVIA describes the data as being used for tracking product demand over time, formulating 'competitive sales strategies,' and developing a further understanding of pharmaceutical distribution." Ex. 2, Keller Rep. ¶ 160 (footnotes omitted).

[2] Keller describes chargeback data as "requests submitted by distributors to labelers to protect distributors from profit loss when drugs are sold to a buyer at less than the distributor paid the labeler for them." *Id.* at ¶ 33.

flagged by monitoring IQVIA data for all manufacturers' opioid medications. She concludes that "Janssen could have stopped up to 15% of all prescriptions written in Summit and Cuyahoga counties between 1997 and 2017, depending on which compliance metric it used." *Id.* ¶ 116.

In another separate "Mallinckrodt Opinion," Ms. Keller seeks to "trace" shipments *by distributors to pharmacies* in Cuyahoga County and Summit County to certain orders that *distributors placed to Mallinckrodt* that were identified by Mallinckrodt's internal algorithm as "peculiar." Ms. Keller attempts to do so by using chargeback data to identify shipments by a distributor of a particular product to pharmacies in Cuyahoga or Summit County that occurred within 30 days of that distributor placing a "peculiar" order with Mallinckrodt. She states that "[w]ith chargeback data, Mallinckrodt was able to see where peculiar orders went," and concludes that 2,860 "peculiar transactions" were shipped by a distributor to Cuyahoga County or Summit County. *Id.* ¶ 158. Keller's opinions, however, are untethered to the questions the jury must answer and the facts, based on unreliable methodologies and data, and should be excluded for several reasons.

First, Keller's methodology for identifying and analyzing what she calls suspicious orders does not satisfy *Daubert*. Keller repeatedly admitted that her use of the term "suspicious orders" was *not* the same as that term of art under the Controlled Substances Act—she instead used it merely to indicate that certain data had "triggered one of the metrics" she had applied. Ex. 1, Keller Tr. 51:6-52:15. Keller admittedly offers no opinion about whether any of these orders was actually suspicious as defined by the CSA or whether any of these orders should have been reported to the DEA. *Id.* at 51:6-52:15, 55:23-56:19. And Keller's analysis is entirely divorced from the real-world due diligence conducted by Manufacturer Defendants after any given order was flagged by an algorithm, which is a necessary second step to determining

whether an order is suspicious and must be withheld and reported to DEA. As a result, Keller's analysis of flagged orders is of no use to the factfinder in determining whether or not certain orders were suspicious under the CSA and instead will only confuse and mislead them.

Second, Keller's Small Labeler Impact opinion is based on the false and unsupported assumption that a physician would have been instantaneously reported to law enforcement and stopped from prescribing another medication ever again immediately after the first time Janssen flagged an order as "suspicious" using any one of Keller's algorithms. Keller's analysis disregards the undisputed evidence in this case that such a thing has never happened and is, in fact, impossible in practice. Keller herself admitted that this opinion is entirely hypothetical and does not take into account any evidence in the case or what might actually occur in reality.

Third, the IQVIA data set underlying Keller's Prescriber and Small Labeler Impact analysis is fundamentally unreliable, because it is undisputed that the IQVIA data set purchased in 2018 by Allergan for purposes of this litigation is static, meaning that it does not reflect the IQVIA data that actually existed at any given moment in time between 1997 and 2018.

Finally, Keller's Mallinckrodt Opinion relies on unsupported assumptions. Keller attempts to trace product sold by distributors to pharmacy customers back to orders placed by those distributors to Mallinckrodt. To do so, Keller simply assumes—based on no facts or evidence—that if Mallinckrodt identified an order from a distributor as "peculiar" as part of its internal review, any bottles of the same product sold by that distributor to pharmacies within 30 days were somehow part of the earlier peculiar order to Mallinckrodt. Ex. 2, Keller Rep. ¶ 158; Ex. 1, Keller Tr. 351:17-22, 393:3-394:15. That assumption is both speculative and false.

For all these reasons, Keller's Opinions fail[3] under *Daubert*.[4]

I. LEGAL STANDARD

The Court has a duty to act as a "gatekeeper" for expert testimony by ensuring that it "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.,* 509 U.S. 579, 597 (1993). "An expert who presents testimony must 'employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Best v. Lowe's Home Ctrs., Inc*., 563 F.3d 171, 177 (6th Cir. 2009). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591. In other words, to qualify for admission, expert testimony must relate to issues "properly before the jury." *Olsen v. American S.S. Co.*, 176 F.3d 891, 894-97 (6th Cir. 1999) (exclusion of expert testimony on doctor's negligence where that issue was not "presented at trial"). "Expert testimony may not be based on mere speculation, and assumptions must be supported by evidence in the record." *Rose v. Truck Centers, Inc.*, 388 F. App'x. 528, 535 (6th Cir. 2010) (citations omitted); *McLean v. 988011 Ontario, Ltd.*, 224 F.3d 797, 800-01 (6th Cir. 2000). When "facts upon which the expert bases [her] testimony contradict the evidence," that "testimony … is inadmissible." *Greenwell v. Boatwright*, 184 F.3d 492, 497 (6th Cir. 1999).

Further, an expert's testimony is inadmissible if it fails Rule 702's "fit" requirement. "Fit requires that the proffered testimony must in fact assist the jury, by providing it with relevant information, necessary to a reasoned decision of the case." *Yarchak v. Trek Bicycle Corp.*, 208 F. Supp. 2d 470, 496 (D.N.J. 2002). To "fit" the case and be admissible under Rule 702, the

[3] This Motion encompasses both Keller's Report and Supplemental Report.

[4] On June 10, 2019, Insys Therapeutics, Inc. and its affiliates each filed a voluntary case under chapter 11 of United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware, which cases are being jointly administered under Case No. 19-11292 (KG). In light of this bankruptcy proceeding, Insys does not join any of the *Daubert* motions or summary judgment motions to be filed in the MDL Track One cases. Separately, Defendant Noramco, Inc. does not join this motion either.

opinion must help the jury "determine a fact in issue. This condition goes primarily to relevance." *Daubert*, 509 U.S. at 591. "Fit" is an issue for consideration at this stage, for it is a "precondition to admissibility" rather than a question of weight. *Hutchison v. Parent*, No. 3:12-cv-320, 2015 WL 1914794, at * 3 (N.D. Ohio Apr. 27, 2015). As such, an expert opinion must also be excluded if it does not assist the triers of fact in performing their duty. Fed. R. Evid. 702.

Finally, "consideration of Rule 403 is included in the *Daubert* analysis," *United States v. LaVictor*, 848 F.3d 428, 444 (6th Cir. 2017), *cert. denied*, 137 S. Ct. 2231 (2017), and under Rule 403, "[t]he court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." *United States v. Collins*, 799 F.3d 554, 588 (6th Cir. 2015). "Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it," *Daubert,* 509 U.S. at 595 (quoting Weinstein, Rule 702 of the Federal Rules of Evidence is Sound, 138 F.R.D. 631, 632 (1991)), as the "aura of reliability" surrounding some evidence presents "the prospect of a decision based on the perceived infallibility of such evidence." *United States v. Bonds*, 12 F.3d 540, 567-68 (6th Cir.1993).

II. ARGUMENT

A. Keller's Method for Identifying Flagged Orders Is Unreliable and Would Mislead Rather Than Assist the Jury.

1. No Competent Evidence Indicates That the Criteria Applied by Keller Actually Identify "Suspicious Orders" Under the CSA.

Keller identifies flagged orders that Plaintiffs will purportedly (but, to date, have not) argue should be deemed "suspicious" orders that Manufacturer Defendants could have flagged, withheld, and reported. But Keller's opinions cannot support such a conclusion and do not meet the requirements of *Daubert* because she merely identifies flagged orders, *i.e.*, *anything* that hit

on *any* of the 16 algorithms run across IQVIA and chargeback data. Keller herself admits that her "flagged" orders indicate only that those orders triggered one of the algorithms she applied, which is ***not*** the same meaning as the term "suspicious" used in the CSA.[5] Although the usefulness of Keller's analysis rises and falls on whether her methodology reliably identifies "suspicious orders" within the meaning of the Controlled Substances Act, she herself admits that it does not. Ex. 1, Keller Tr. 51:6-52:15; 55:23-56:19; 111:12-112:3; 146:5-9; 148:6-14; 210:7-13; 210:21-211:7.

Indeed, none of Plaintiffs' experts, nor any DEA witness, has testified that the fact that an order triggers any of these 16 algorithms means the order is "suspicious" under the CSA.[6] And Keller testified that she cannot opine as to whether any manufacturer should have used some or all of her algorithms as part of a suspicious order monitoring system, *id*. 50:14-51:5, whether any order identified by those algorithms should have been reported to the DEA, *id*. 55:23–56:19, or whether any such order was "suspicious" within the meaning of the Controlled Substances Act (or DEA's interpretation of the CSA), *id*. 51:6–52:15; *see also id*. 238:12-17. Because Keller is not deciding what should have been flagged as "suspicious" under the CSA—the foundation of Plaintiffs' diversion-based claims[7]—she does not offer anything that would be remotely helpful

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[5] Ex. 1, Keller Tr. 52:6-15 ("Q. You don't mean to use "suspicious" as a technical term meaning suspicious under the Controlled Substances Act, right? … A. Yes, when I say 'suspicious,' I mean that they have…triggered one of the metrics").

[6] *See, e.g.,* Ex. 3, Rafalski Report at 12-13 ("Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System ("SOMS"), the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders..."); Ex. 6, Prevoznik Tr. 180:3-11 ("Q. And there's no single feature that makes a suspicious order monitoring system compliant, correct? A. Correct."); Ex. 7, Prevosnik Tr. 1211:9-18 ("Q. But standing alone, without follow-up due diligence, it is not necessarily always possible to determine whether an order that is an unusual size, unusual pattern or frequency is, by itself, for that reason, indicative of diversion, correct?… THE WITNESS: Correct.").

[7] *See, e.g.*, TAC ¶¶ 498-500; *see also* Pls' Mot. for Partial SJ of Defs' Duties Under the CSA, Dkt. No. 1719 ("Plaintiffs have asserted several claims for which the Defendants' compliance with the CSA is relevant, including claims under the federal Racketeer-Influenced and Corrupt Organizations ('RICO') Act, Ohio's parallel RICO statute, and Ohio's absolute public nuisance law.").

to the jury in determining whether a registrant failed to monitor and report a suspicious order under that statute.

Keller's methods are also flawed because she applies *the same* 16 algorithms to six different corporate groups of defendants manufacturing and/or selling different products, without regard to whether any of the defendants actually applied any of the algorithms.[8] DEA representatives and Plaintiffs' own DEA expert testified that a company's suspicious order monitoring program must be tailored to its particular business model and medications.[9] Even if a particular criterion is used by one manufacturer for its own internal analysis, there is no reason to believe that such a metric would be appropriate for another manufacturer.

Untethered to the statutory standard that is the foundation of Plaintiffs' diversion-based claims as well as any relevant evidence, Keller's opinions would affirmatively mislead and confuse the jury rather than help them decide any disputed issue in the case. They are inadmissible under Rule 702, Daubert, and Rule 403, and should be excluded on this basis alone.

2. Keller's Algorithm Does Not Consider Due Diligence Conducted After Algorithmic Flagging of Certain Orders.

As DEA representatives repeatedly testified, an order flagged as possibly suspicious may be determined through due diligence not to be suspicious, and therefore need not be reported to DEA.[10] Keller's purely mathematical model, however, fails to account for the due diligence

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[8] Further, for at least the Janssen defendants, Keller failed to apply, compare, or even reference the algorithm Janssen actually *did* apply. Ex. 1, Keller Tr. 213:25-215:10 (admitting that she did not apply Janssen's algorithm and that her counsel (incorrectly) advised her it did not exist).

[9] *See, e.g.*, Ex. 6, Prevoznik Tr. 180:3-11 ("Q. And there's no single feature that makes a suspicious order monitoring system compliant, correct? A. Correct. Q. And the DEA leaves it up to the registrant to design a system that works with its own business model and customer base, correct? A. Correct."); Ex. 9, Rannazzisi Tr. 420:13-21 ("Q. All right. So it's a business decision based upon, I guess it might be different for a manufacturer than a distributor than a seller, et cetera? … [A]: Yes."); Ex. 4, Rafalski Tr. at 57:15-58:4, 58:19-59:11, 155:7-156:10, Ex. 5, Rafalski Tr. Vol. 2 447:20-449:5, 484:9-13.

[10] *See* Ex. 7, Prevosnik Tr. 1211:9-18 ("Q. But standing alone, without follow-up due diligence, it is not necessarily always possible to determine whether an order that is an unusual size, unusual pattern or frequency is, by itself, for that reason, indicative of diversion, correct?… THE WITNESS: Correct."); Ex. 8, Rannazzisi Tr. 326:5-11 ("A. …

used to determine whether a flagged order is suspicious. Indeed, Keller admitted that she has "no opinions on the real world," Ex. 1, Keller Tr. at 57:19-25; *see also id*. 59:12-20, 154:6-20, and she "didn't look at . . . how each order was processed, monitored, flagged, unflagged or released, et cetera." *Id*. at 236:5-15. Indeed, Keller did not undertake to determine whether any transaction was actually suspicious, following due diligence or otherwise. *Id*. at 155:21-156:7.

Keller's failure to account for this fundamental aspect of suspicious order monitoring renders her methods unreliable. Even Plaintiffs' experts and the DEA agree that due diligence is a critical component of the suspicious order monitoring process, as several DEA witnesses testified, because orders that may trigger an algorithm or appear unusual at first glance may (and often do) turn out to be perfectly legitimate once diligence is complete.[11] Keller's opinion tells only a small part of the story and, without accounting for the remainder of the suspicious order analysis, is not helpful and likely to mislead the jury.

B. Keller's Method for Counting Orders That Supposedly Could Have Been Stopped Despite Janssen Being a "Small Labeler" Is Unreliable.

Keller also purports to model what would have happened if a so-called "small labeler" like Janssen—which she calculates had a market share of between 0.1 percent and no more than 0.9 percent in Summit and Cuyahoga Counties, *see* Ex. 1, Keller Tr. 221:22-222:5—had reported to the DEA the prescriptions she flags by running her 16 algorithms across IQVIA data.[12] As an

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You might have the greatest system in the world but if you are not following your own protocols, if you are not looking at each individual order that the system kicks out, *doing due diligence*, maintaining effective controls against diversion, then the system is worthless") (emphasis added); Ex. 10, K. Wright Tr. 142:16-25 ("It's quite possible that, upon further investigation, the registrant could resolve the question of whether [a possible suspicious order] is suspicious and make the decision to go ahead and ship[.]"); Ex. 7, Prevoznik Tr. 1038:22-1039:8 (confirming that due diligence is necessary to overcome the limitations of ARCOS data).

[11] *See* n. 7, *supra*.

[12] Ex. 2, Keller Rep. ¶ 34 ("if Janssen – the defendant labeler with the second smallest market share in Summit and Cuyahoga counties – had reported suspicious activity, prescriptions for millions of dosage units could have been stopped in Summit and Cuyahoga counties"); *see also id*. at ¶¶ 114-116.

initial matter, this analysis is unreliable for the same reasons identified in the preceding section: Nothing supports the notion that the prescriptions Keller flagged were *actually* suspicious as the CSA and its implementing regulations and DEA define that term. Ex. 1, Keller Tr. 51:6-52:15.

But the Small Labeler Impact Opinion is additionally unreliable due to yet another false assumption, namely, that each prescriber would have been stopped from prescribing ***all opioids immediately after his or her first prescription was reported to law enforcement and immediately after being flagged by any of Keller's 16 criteria***. *Id*. at 231:12-232:11; 261:1-262:11. Keller has no expertise in how this might happen, *id*. at 60:3-9, 257:16-25, and admitted that she has no reason to believe her instant-stop assumption is correct, *id*. at 232:12-18. And in fact, Keller's assumption is plainly erroneous and has absolutely no basis in the evidence or reality: Fewer than 1 percent of suspicious order reports lead to the revocation of a prescriber's DEA license (which authorizes the prescription of opioid medications), Ex. 11, Holifield Rep. at 40-42, and even those rare revocations are not instantaneous. Any diversion investigation by the DEA or law enforcement takes significant time, as Keller's own report admits. *See* Ex. 2, Keller Rep. ¶ 96 (detailing two-year investigation into flagged prescriber); Ex. 1, Keller Tr. 256:23-257:10 (acknowledging two-year investigation from report).

Given her entirely unsubstantiated assumptions and repeated admissions that her opinion is hypothetical and has no basis in the real world, *see e.g.*, Ex. 1, Keller Tr. 57:19-25; 226:17-22; 259:19-260:11; *see also* 229:22-230:12; 232:12-18; 257:16-259:3, Keller's estimates of how many orders would have been stopped by the Janssen Defendants' reporting are wildly inflated, unreliable, and will only mislead the jury. Keller should not be permitted to give these inflated numbers a veneer of reliability by means of her expert testimony at trial. *Bonds*, 12 F.3d at 567-68.

C. Keller's Prescriber and Small Labeler Opinions Based on IQVIA Data Are Inadmissible Because the IQVIA Data Set Is Not Reliable.

Keller's opinions based on the IQVIA data are unreliable for additional reasons, both because of how the firm IQVIA maintains its data and because of how Keller incorporated that data in her analysis. Keller's opinions based on IQVIA data are thus inadmissible.

For an expert's opinion to be admissible, the data underlying her opinion must be reliable. An expert's opinion "fail[s] the reliability requirements of *Daubert* and the Federal Rules of Evidence" where "the underlying data" on which the expert relies is "not sufficiently reliable." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291-95 (3d Cir. 2012) (affirming exclusion of expert's damages calculation where expert "was unaware of the qualifications of the individuals who prepared the document" on which he relied "or the assumptions on which the estimates were based"); *see also Spangler Candy Co. v. Tootsie Roll Industries, LLC*, 372 F. Supp. 3d 588, 596 (N.D. Ohio 2019) (excluding portion of expert report where expert "was unable to attest to [the] reputation" of sources relied upon, and "did not verify the underlying data and methodology used to reach conclusions upon which he relie[d]").

As an initial matter, Keller had no basis to know whether any manufacturer actually had in its possession the same IQVIA data she used, which Allergan purchased from IQVIA in 2018 for this litigation. Ex. 1, Keller Tr. 102:12-103:7; 104:9-105:19. Keller testified that she assumed that Manufacturer Defendants "could have purchased" IQVIA data for the twenty-year period her report spans. *Id*. Keller offers no basis for concluding Manufacturer Defendants had an obligation to acquire IQVIA data for use in their suspicious order monitoring programs.

Even more fundamentally, however, the use of IQVIA data in Keller's analysis is flawed because of the way that data works and how it is maintained: Instead of being a static set of data for each calendar year, IQVIA data is dynamic, changing year to year to reflect changes in the

landscape of information it encompasses. Ex. 12, Dec. 14, 2018 Letter from J. Davis to P. Weinberger, at 2. As IQVIA reported and defense counsel relayed to Plaintiffs, IQVIA "does not maintain historical order information for past opioid-related purchases in the ordinary course of business or copies of historic data deliverables given the overwhelming quantity of such data and the associated storage costs," and "any attempt to repopulate data [would] require writing new business rules and making educated assumptions, but can in no way reflect the precise deliverables that each Defendant previously received." *Id.*[13] Thus, the 2018 IQVIA data Allergan purchased does not provide an accurate representation of what Allergan would have relied on historically prior to 2018 had Allergan actually had this data at that time, and the same is true of any other defendants who had access to IQVIA data. Keller's reliance on IQVIA data that is not based in the real world makes her report inaccurate and unreliable, and as a result, her opinions based on analysis of that data should be excluded from the jury's consideration.

D. Keller's Attempt To Trace Mallinckrodt Orders Downstream Is Inadmissible Under FRE 702.

Recognizing that Mallinckrodt never shipped a suspicious order to Cuyahoga or Summit County, Plaintiffs ask Ms. Keller to "trace" shipments *by distributors to pharmacies* in those counties to certain orders *from distributors to Mallinckrodt* that were identified by Mallinckrodt's internal algorithm as "peculiar." Their apparent theory is that if Mallinckrodt had only refused to fill a "peculiar" order for opioids placed by a distributor, that distributor could not have later shipped opioids to a pharmacy in the Track One jurisdictions.

[13] IQVIA also reported other limitations, including that it "is only able to review what was historically delivered from its 'subnational data offerings' and only for a more limited timeframe than 1998-2018, the period covered by Judge Polster's order," that it "cannot recreate data deliverables specific to opioid products without access to legacy information from Defendants that is unavailable in most cases," and that "any recreated list of historic deliverables would necessarily be incomplete and inaccurate because any post hoc list would reflect only deliverables transmitted at the end of each calendar year, omitting ad-hoc requests or mid-year contract changes to data offering." Ex. 12, Dec. 14, 2018 Letter from J. Davis to P. Weinberger, at 2.

Ms. Keller's effort fails, however, because no data exist that would allow Ms. Keller or anyone else to "trace" distributor shipments to pharmacies back to orders (peculiar or otherwise) placed with Mallinckrodt. This leads Ms. Keller to make an arbitrary and unsupportable assumption: that any shipment by a distributor of a particular product within 30 days of that distributor placing a "peculiar" order to Mallinckrodt was necessarily fulfilled with bottles shipped by Mallinckrodt in response to the distributors' peculiar order. In other words, if the distributor placed a peculiar order for hydrocodone to Mallinckrodt, every bottle of hydrocodone that distributor shipped to pharmacies for the next 30 days must have come from the peculiar order. That assumption is as illogical as assuming that, if Ford sent five Ford Explorers to a Cleveland dealership on June 1, and the dealership sold a Ford Explorer to a family on June 29, the family drove home in a car that was part of the June 1 delivery. In fact, of course, the family may have purchased an Explorer that was delivered to the dealership before or after June 1, as part of a small (non-peculiar) delivery or a large one. So too here. Ms. Keller simply cannot say with any reliability which Mallinckrodt shipment provided the product that a distributor later used to fill an order from a pharmacy in the Track One counties.

Ms. Keller's blind speculation that Mallinckrodt's data *could* allow someone to trace bottles from downstream sales through "chargeback data" is refuted by the data itself—and is certainly not a reliable basis for her opinion.[14] Notably, Ms. Keller did not review Mallinckrodt's sales data before opining in her report that Mallinckrodt's sales could be traced to later shipments by distributors to pharmacies. Ex. 1, Keller Tr. 350:22-351:22. And even after reviewing such information when Mallinckrodt's expert, Edward Buthusiem, submitted his

[14] Chargeback requests typically include information about the distributor, the distributor's customer, the date of the sale for which the distributor is requesting a chargeback, the product sold (identified by its NDC code), the quantity sold, and the price paid by the distributor's customer. Ex. 13, Buthusiem Rep. ¶ 14.

report, Ms. Keller could not identify any data allowing the type of tracing she posits. *Id*. at 351:17-22; 354:15-359:14. Although Ms. Keller speculated that Mallinckrodt sales data might contain an "order number" allowing one to connect a distributor sale to a pharmacy with a distributor's order to Mallinckrodt, *id*. at 393:3-394:15, she could not point to one. That is because none exists. As Mr. Buthusiem's report makes clear, and Ms. Keller does not refute, "chargeback requests from distributors to manufacturers do not indicate what specific product inventory (*i.e.*, which particular bottles or packages) the distributor used to fulfill the sale to the downstream registrant" and do not include information linking the chargeback to a sale by Mallinckrodt. Ex. 13, Buthusiem Rep. ¶¶ 13-14; Dep. Tr. 350:2-17; 396:21-397:25.

Unsurprisingly, Ms. Keller's unjustified assumptions lead to unreliable results. As Mr. Buthusiem demonstrates, the downstream sales Ms. Keller purports to trace back to peculiar orders (*see* Ex. 2, Keller Rep. at Table 74) can just as easily be "traced" to non-peculiar orders that supplied the same product to the distributor's inventory.[15] Ex. 13, Buthusiem Rep. ¶ 30. Ms. Keller's opinion thus offers no more than blind guesses about whether a particular bottle shipped by a distributor originated from a particular order. Such unreliable results, based on unreliable assumptions, must be excluded under *Daubert*. 509 U.S. at 597 (opinion must have "reliable" scientific and evidentiary "foundation"); *see also General Elec. Co. v. Joiner*, 522 U.S. 136, 144-45 (1997) (expert may not base opinion on speculation, conjecture or subjective belief); *Greenwell*, 184 F.3d at 497 (expert testimony based on facts that "contradict the evidence" "is inadmissible").

[15] Ms. Keller testified that she has no expertise in, and did not consider, any distributor's inventory management practices or contracts with manufacturers when forming her opinions. Ex. 1, Keller Tr. 365:19-366:17. Indeed, Ms. Keller's selection of a 30-day window in attempting to "trace" peculiar orders to downstream sales is inconsistent with standard distributor management practices. Ex. 13, Buthusiem Rep. ¶¶ 28-29.

CONCLUSION

For the reasons identified above, the Court should exclude Lacey Keller's testimony in its entirety.

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Respectfully submitted,

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[16] Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their pending motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this motion as a result of the Court's deadline to file dispositive and Daubert motions, and, thus, they do not waive and expressly preserve their pending personal jurisdiction challenges.

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CERTIFICATE OF SERVICE

I, Charles C. Lifland, hereby certify that the foregoing document was served on June 28, 2019 via electronic transfer to all counsel of record, consistent with the Court's order.

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